IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

PAR PHARMACEUTICAL, INC., PAR STERILE PRODUCTS, LLC, and ENDO PAR INNOVATION COMPANY, LLC,	)	
Plaintiffs,	)	C.A. No. 18-823-CFC
v.	)	**PUBLIC VERSION**
EAGLE PHARMACEUTICALS INC.,	)	
Defendant.	)	

LETTER TO THE HONORABLE COLM F. CONNOLLY
FROM BINDU A. PALAPURA

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VIA ELECTRONIC FILING
The Honorable Colm F. Connolly
United States District Judge
J. Caleb Boggs Federal Building
844 N. King Street
Unit 31, Room 4124
Wilmington, DE 19801-3555

Re: *Par Pharm., Inc. v. Eagle Pharms., Inc.*, C.A. No. 18-823-CFC

Dear Judge Connolly:

Eagle respectfully requests leave to move for summary judgment of noninfringement, because [redacted].[1] The motion would resolve all remaining infringement claims.

In a typical ANDA case such as this, the alleged infringer's product is not FDA-approved or marketed. Therefore, "[t]he relevant inquiry is whether the patentee has proven by a preponderance of the evidence that the alleged infringer ***will likely*** market an infringing product." *Glaxo, Inc. v. Novopharm, Ltd.*, 110 F.3d 1562, 1569 (Fed. Cir. 1997). Par cannot meet its burden for two independent reasons.

First, when an ANDA "directly addresses the question of infringement" by specifying a parameter outside the claim limitations, it "mandates a finding of no literal infringement." *Bayer AG v. Elan Pharm. Research Corp.*, 212 F.3d 1241, 1249 (Fed. Cir. 2000). In those circumstances, "'[b]ecause drug manufacturers are bound by strict statutory provisions to sell only those products that comport with the ANDA's description of the drug,' the ANDA itself dominates the analysis." *Ferring B.V. v. Watson Labs., Inc.-Florida*, 764 F.3d 1401, 1408 (Fed. Cir. 2014) (citation

[1] Par has not asserted infringement under the doctrine of equivalents.

omitted). And the ANDA can be approved only if the applicant demonstrates its product will comply with its specifications. *See* 21 C.F.R. § 314.127(a); *Bayer*, 212 F.3d at 1249-50.

Bayer is instructive. The ANDA there required a "specific surface area ('SSA')" outside the claimed range. 212 F.3d at 1244. The Federal Circuit affirmed the district court's grant of summary judgment because the defendant could not legally sell an infringing product under its specification, and therefore the "ANDA mandate[d] a finding of no literal infringement." *Bayer*, 212 F.3d at 1249-50.

Here, [redacted] Eagle's ANDA does not allow the sale of an infringing product and therefore "mandates a finding of no infringement." *Bayer*, 212 F.3d at 1249.

Notably, the patentee in *Bayer* argued that testing data showed the defendant's SSA could decrease, calling into question its ability "to comply with its SSA specification and thus produce a noninfringing product." 212 F.3d at 1348. The Federal Circuit disagreed, stating those were "not ***material*** factual issues because [the Act] prohibits [the defendant] from selling any product that does not meet its ANDA's requirements," with severe penalties for non-compliance. *Id.* at 1250.

A similar result was reached in *In re Brimonidine Patent Litigation* [redacted] he defendant's ANDA specified a pH outside the claimed range. 643 F.3d 1366, 1376-77 (Fed. Cir. 2011). The district court found infringement based on stability data showing a pH change over time. *Id.* at 1377. But the Federal Circuit reversed, stating "[w]e cannot assume that [the defendant] will not act in full compliance with its representations to the FDA." *Id.* at 1378.

Any reliance by Par on Eagle's data likewise should be rejected.[2]

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[2] In a successor case to *Bayer—Bayer AG v. Biovail Corp.*, 279 F.3d 1340 (Fed. Cir. 2002)—the court looked beyond the ANDA only because testing of the "***actual commercial product***" approved and being sold showed infringement. *Id.* at 1349. Therefore, the court did "not ask what [defendant] will likely market, but what [defendant] has ***actually marketed***." *Id*. Not so here, where Eagle is not yet selling its ANDA product, and its ANDA controls. *Bayer*, 212 F.3d at 1249.

Second, even if Eagle's ANDA did not control, [redacted] (CSF, ¶¶18-19, 29, 36, 41.) [redacted] (CSF, ¶¶15, 22-23, 35, 40.) [redacted] (CSF, ¶¶42.)

Nevertheless, Par speculates that Eagle's product [redacted]. (CSF, ¶32.) But Par cannot carry its burden with such speculation. *Ferring*, 764 F.3d at 1409-10. In *Ferring*, "the ANDA specification [did] not itself resolve the question of infringement," so it was necessary to look to testing data. *Id.* at 1409. The district court found infringement based on four test results meeting the claims out of hundreds. *Id.*

The Federal Circuit reversed, calling those results "outliers" and rejecting that "reliance on such anomalies proves infringement by a preponderance of the evidence." *Id.* at 1409–10. So too here. To support its speculation, Par points to [redacted] (CSF, ¶32.) [redacted] (CSF, ¶30.) As in *Ferring*, this [redacted] cannot support a finding that Eagle will "likely market an infringing product." *Glaxo*, 110 F.3d at 1570; *see Ferring*, 764 F.3d at 1409-10.[3]

For these reasons, Par cannot meet its burden of proving infringement as a matter of law, and Eagle respectfully requests leave to move for summary judgment on these bases.

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[3] Any argument that "the FDA will require [Eagle] to amend [its] ANDA[] at some unspecified point in the future" also cannot avoid summary judgment. *AstraZeneca Pharm. LP v. Apotex Corp.*, 669 F.3d 1370, 1380–81 (Fed. Cir. 2012); *see also Par Pharm., Inc. v. Luitpold Pharm., Inc.*, 2017 WL 452003, at *6 (D.N.J. Feb. 2, 2017) (granting judgment on the pleadings and rejecting Par's infringement theory based on "speculation that future, uncertain amendments to [defendant's] ANDA will infringe Par's patents").

Respectfully,

/s/ Bindu A. Palapura

Bindu A. Palapura

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cc: Clerk of the Court (via hand delivery)
Counsel of Record (via electronic mail)